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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 10/076,892      | 02/14/2002  | Bradley L. Christenson | 19654-243493        | 4377             |

25764 7590 03/19/2003

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/076,892             | CHRISTENSON ET AL.  |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Micah-Paul Young       | 1615                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
  - 2a) This action is **FINAL**.      2b) This action is non-final.
  - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 1-27 is/are pending in the application.
    - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
  - 5) Claim(s) \_\_\_\_\_ is/are allowed.
  - 6) Claim(s) 1-27 is/are rejected.
  - 7) Claim(s) \_\_\_\_\_ is/are objected to.
  - 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                              |                                                                              |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

## DETAILED ACTION

**Acknowledgement of papers received:** Information Disclosure Statement 02/14/02 and

Preliminary Amendment entered 1/22/03 filed 04/02/02

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Osawa et al (USPN 3,873,588). The claims are drawn to an extended release tablet comprising granules of potassium chloride and a thermoplastic cellulose ether, where the ether is ethyl cellulose.

Osawa et al teaches an extended release tablet comprising granules of potassium chloride and ethyl cellulose (col. 5, lin. 45 – 49; col. 13, in. 3 – 8). These disclosures render the claims anticipated.

3. Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lippmann et al (USPN 4,259,315). Claims 1, 3 and 5 are drawn to a granule comprising potassium chloride and a thermoplastic cellulose ether, where the thermoplastic ether is ethyl cellulose. The ethyl cellulose has a viscosity between 10 – 30 cP.

Lippmann et al teaches a controlled release formulation comprising granules of potassium chloride and a thermoplastic cellulose ether. The cellulose ether of the reference is

preferably ethyl cellulose has a viscosity of 22 cP (Abstract; col. 4, lin. 40 – 55). These disclosures render the claimed invention anticipated.

4. Claims 1 – 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen (USPN 5,397,574). Claims 1 – 5 are drawn to granules containing potassium chloride with a mesh size between 20 and 60, and ethyl cellulose having viscosity between 10 and 30 cP.

Chen teaches a controlled release tablet of potassium chloride, where the granules that make up the tablet are coated with ethyl cellulose (Abstract). Chen further teaches that the ethyl cellulose of the invention has a viscosity of 10 cP while the potassium chloride particles have a mesh size between 20 and 50 (col. 2, lin. 31 – 35; Example 1). These disclosures render the claimed invention anticipated.

5. Claims 1-5, 8, 10, 11 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsiao et al (USPN 4,863,743). Claims 1 – 4 are drawn to a granule comprising potassium chloride and a thermoplastic cellulose ether, where the thermoplastic ether is ethyl cellulose. The ethyl cellulose has a viscosity between 10 – 30 cP, while the potassium chloride crystals are between 20 and 60 mesh. Claims 5, 8, 10 and 11 are drawn to an extended release tablet made from the granules where the tablet contains 10, 15 or 20 mEq potassium. Claim 27 is drawn to a method of customizing a patient's potassium chloride regimen.

Hsiao et al teaches an extended release tablet containing granules comprising potassium chloride and ethyl cellulose. The ethyl cellulose used by the reference has a viscosity ranging from 6 – 40 cP. The tablet contains 20mEq of potassium, and would be administered to a patient

in need in order to supplement their potassium requirements (col. 3, lin. 54 – 60; col. 4, lin. 51 – 68; col. 5, lin. 43 – 56). These disclosures render the claimed invention anticipated.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1- 16 and 27 – 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsiao et al (USPN 4,863,743). Claims 1 – 4 are drawn to a granule comprising potassium chloride and a thermoplastic cellulose ether, where the thermoplastic ether is ethyl cellulose. The ethyl cellulose has a viscosity between 10 – 30 cP, while the potassium chloride crystals are between 20 and 60 mesh. Claims 5 – 11 are drawn to an extended release tablet containing the granules of claims 1 – 4. The claims recite that the tablet is substantially free from surfactants and other processing aids and agents. The claims recite specific concentrations and ranges of the essential components. Claims 12 – 16 are drawn to tablet comprising a plurality of the granules

of the invention. Claim 27 is drawn to a method of customizing a patient's potassium chloride regimen. Claims 28 – 30 are drawn to a tablet comprising granules, 15 mEq of potassium, and an extended release coating of ethylcellulose. The tablet is recited to be free of surfactants, and processing aids.

As discussed above Hsiao et al teaches many essential elements of the claimed invention. The examples of the reference include other excipients, yet the reference discloses that these excipients are completely optional. Barring a comparative showing of unexpected results, and criticality to the composition being substantially free of surfactants and other agents, it is the position of the examiner that these limitations do not impart patentability, and does not distinguish the claimed invention from the prior art.

With regard to claims 7, 8, 13, 14 and 28 which are drawn to tablets containing specific concentrations of potassium chloride and ethyl cellulose. Claims 7 and 13 recite the tablets to have approximately 17.4% potassium chloride, while claim 8 and 14 recite the tablet to have a concentration of 13.5%. The reference teaches the potassium chloride to be present in a concentration of 79%, and in dosage of 15 mEq with an ethyl cellulose content of 11.9%. It would be obvious to one of ordinary skill in the art to modify the formulation to achieve the optimal results. Furthermore applicant is reminded that merely reciting the optimal working ranges in a composition does not impart patentability, when the general conditions of the composition are met. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With these things in mind, one of ordinary skill in the art would be motivated to modify the teachings of the reference to achieve an optimal formulation. Since the formulation does not require further excipients, a skilled artisan would be motivated to formulate a tablet from granules of the potassium chloride and ethyl cellulose without an addition of further components, in order to achieve an optimal release profile. It would have been obvious to a skilled artisan at the time of invention, to modify the teachings and suggestions of the reference with an expected result of a controlled release tablet containing potassium chloride and ethyl cellulose granules.

9. Claims 17 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsiao et al (USPN 4,863,743) in view Tamás et al (USPN 4,748,023). Claims 17 – 21 are drawn to a method of ethylcellulose coated potassium chloride granules comprising forming a fluidized bed of the potassium chloride particles, spraying the crystals with a solvent/coating solution, and then removing the solvent during the drying process. This takes place at a dew point between 10 and 20 degrees Celsius. Claims 22 – 26 are drawn to a method of making ethylcellulose coated potassium chloride. The process is identical to the process of claims 17 – 21 only that the

components of the solvent solution are recited as methyl alcohol, and water. Also concentrations for each of the components are recited as well.

Hsiao et al teaches a tablet comprising granules of potassium chloride coated with ethyl cellulose. The reference teaches that the granules are coated in a fluidized bed, with a solvent solution including methyl alcohol and distilled water. The solvents are removed during the drying step, which provides granules coated with ethyl cellulose. As discussed above the reference discloses that the tablet can optionally contain excipients but they are not required. The reference is silent to the dew point temperature at which the coating process occurs. The use of a fluidized bed to create coated particles is well known in the art, and the temperature at which the coating occurs can vary depending upon the practitioners. These variations can be determined through routine experimentation by one of ordinary skill in the art. As seen in Tamás, which discloses a fluidized bed coating process making potassium chloride granules, where the temperature is 20 degrees Celsius.

The reference provides identical granules to those of the claimed invention, produced by the same process (a fluidized bed) as applicant's the burden is now shifted to applicant to show a patentable difference between the two. Identical products are made through similar processes it is now upon the applicant to show the patentable distinction of the two granules. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences.

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*See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

With this in mind one of ordinary skill in the art would be motivated to follow the teachings and suggestions of the art in order to produce coated granules that allowed for more optimized bioavailability. A skilled artisan seeing the knowledge in the art to modify a fluidized bed process as exhibited by Tamás, would be motivated to modify the concentrations and temperature of the process in order to optimize the output of coated granules and to maximize the bioavailability of the final product. It would have been obvious to a skilled artisan to follow the teachings and suggestion in the art with an expected result of a process, which produces coated potassium chloride granules.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

*THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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